



## Therapeutic Class Review<sup>SM</sup>

### moxifloxacin hydrochloride ophthalmic solution 0.5% (Vigamox<sup>®</sup>)

March 2005

#### New Product for Review

moxifloxacin ophthalmic solution 0.5% (Vigamox)  
(Alcon)

**Dossier Provided by Manufacturer:** Yes

#### Available Therapeutic Alternative(s)

Preferred/Formulary	Non-Preferred/Non-Formulary
ciprofloxacin ophthalmic 0.3% solution (generic)	levofloxacin ophthalmic 0.5% solution (Quixin <sup>TM</sup> )
ofloxacin ophthalmic 0.3% solution (generic)	gatifloxacin ophthalmic 0.3% solution (Zymar <sup>TM</sup> )

#### Executive Summary

- Moxifloxacin (Vigamox) ophthalmic solution is a fourth generation fluoroquinolone antibacterial product that does not contain benzalkonium chloride and is approved for treating bacterial conjunctivitis in adults and children.
- Unlike ciprofloxacin, ofloxacin, levofloxacin (Quixin) and gatifloxacin (Zymar), clinical studies with moxifloxacin are of poor quality and not published in peer-reviewed journals. These studies report that moxifloxacin (Vigamox) is:
  - non-inferior to ciprofloxacin and ofloxacin ophthalmic solutions for treating bacterial conjunctivitis in adults and children.
  - similar to placebo for treating bacterial conjunctivitis in infants <30 days old.
- There is no evidence to support the use of moxifloxacin (Vigamox) as a prophylactic agent during ophthalmologic procedures.

#### Conclusion

Moxifloxacin (Vigamox) is non-preferred/non-formulary because this product offers no additional clinical advantages over other formulary options to treat bacterial conjunctivitis in adults and children.

## Products

Drug Product	Date of FDA Approval	FDA Approved Indication(s)	Dose Route	AWP Cost*	Potential Off-Label Use(s)
ciprofloxacin 0.3% ophthalmic solution (generic) and ointment (generic)	03/30/1998	Treatment of a) Corneal Ulcers infections caused by susceptible strains of <i>Pseudomonas aeruginosa</i> , <i>Serratia marcescens</i> , <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , <i>Streptococcus pneumoniae</i> , and <i>Streptococcus</i> (Viridans Group), and b) Conjunctivitis caused by susceptible strains of <i>Haemophilus influenzae</i> , <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , and <i>Streptococcus pneumoniae</i> .	Ophthalmic	5 mL \$7.93**	All ophthalmic antibiotic solutions have been used for various eye surgical prophylaxis, blepharitis, keratitis, endophthalmitis, and in neonates.
ofloxacin 0.3% ophthalmic solution (generic)	07/30/1993	Treatment of infections caused by susceptible strains of the following bacteria in Bacterial conjunctivitis (Gram-positive bacteria: <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , and <i>Streptococcus pneumoniae</i> . Gram-negative bacteria: <i>Enterobacter cloacae</i> , <i>Haemophilus influenzae</i> , <i>Proteus mirabilis</i> , and <i>Pseudomonas aeruginosa</i> ) and Corneal ulcers (Gram-positive bacteria: <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , <i>Streptococcus pneumoniae</i> . Gram-negative bacteria: <i>Pseudomonas aeruginosa</i> and <i>Serratia marcescens</i> . Anaerobic species: <i>Propionibacterium acnes</i> ).	Ophthalmic	5 mL \$7.00**	
gatifloxacin 0.3% ophthalmic solution (Zymar)	03/28/2003	Treatment of bacterial conjunctivitis caused by susceptible strains of a) aerobic Gram-Positive Bacteria ( <i>Corynebacterium propinquum</i> , <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , <i>Streptococcus mitis</i> , and <i>Streptococcus pneumoniae</i> ) and b) Aerobic Gram-Negative Bacteria ( <i>Haemophilus influenzae</i> )	Ophthalmic	5 mL \$54	
levofloxacin 0.5% ophthalmic solution (Quixin)	08/18/2000	Treatment of bacterial conjunctivitis caused by susceptible strains of a) aerobic Gram-Positive Bacteria ( <i>Corynebacterium</i> species, <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , <i>Streptococcus pneumoniae</i> , <i>Streptococcus</i> (Groups C/F), <i>Streptococcus</i> (Group G) and Viridans group streptococci) and b) susceptible strains of aerobic Gram-Negative Bacteria ( <i>Acinetobacter lwoffii</i> , <i>Haemophilus influenzae</i> and <i>Serratia marcescens</i> ).	Ophthalmic	5 mL \$49	
moxifloxacin ophthalmic solution 0.5% (Vigamox)	04/15/2003	Treatment of bacterial conjunctivitis caused by susceptible strains of a) Aerobic Gram-positive microorganisms ( <i>Corynebacterium</i> species, <i>Micrococcus luteus</i> , <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , <i>Staphylococcus haemolyticus</i> , <i>Staphylococcus hominis</i> , <i>Staphylococcus warneri</i> , <i>Streptococcus pneumoniae</i> and <i>Streptococcus viridans</i> group) b) Aerobic Gram-negative microorganisms ( <i>Acinetobacter lwoffii</i> , <i>Haemophilus influenzae</i> and <i>Haemophilus parainfluenzae</i> ) and c) Other microorganisms ( <i>Chlamydia trachomatis</i> ).	Ophthalmic	3 mL \$53	

\*AWP (average wholesale price) based on First Data Bank as of December 30, 2004 for one month therapy

\*\*Based on Maximum Allowable Cost (MAC) as of September 2004 for one month supply

## References

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5. Conjunctivitis: American Academy of Ophthalmology. Preferred Practice Patterns. [http://www.aao.org/aao/education/library/ppp/upload/Conjunctivitis\\_.pdf](http://www.aao.org/aao/education/library/ppp/upload/Conjunctivitis_.pdf)
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